K010520

MAY - 7 2001

# Section 3
# GEM Premier 3000: Addition of Glucose / Lactate Parameters - 510(k) Summary
# (Summary of Safety and Effectiveness)

**Submitted by:**

Instrumentation Laboratory Company
113 Hartwell Avenue
Lexington, MA 02421
Phone: 781-861-4285
Fax: 781-861-4464

**Contact Person:**

Reba Poirier, Regulatory Affairs Process Manager
Phone: 781-861-4285 / Fax: 781-861-4464

**Summary Prepared:**

February 21, 2001

**Name of the device:**

GEM Premier 3000 – Addition of Glucose and Lactate as Measured Parameters

**Classification name(s):**

| | | |
|---|---|---|
| 75CGA | Glucose Oxidase, Glucose | |
| 862.1345 | Glucose Test System | Class II |
| 75KHP | Lactic Acid, Lactate | |
| 862.1450 | Lactic Acid Test System | Class I (Exempt) |

**Identification of predicate device(s):**

K913806 YSI Model 2300 STAT PLUS Glucose and Lactate Analyzer

**Description of the device/intended use(s):**

The GEM Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples that was cleared for market by K992834. Two new parameters are being added on the GEM Premier 3000 for the quantitative measurements of glucose and lactate (lactic acid) on whole blood and to its associated quality control materials. These new parameters aid in the diagnosis of the patient's acid/base and glucose status.

**Statement of Technological Characteristics of the Device Compared to Predicate Device:**

Glucose and lactate (lactic acid) as measured parameters for use with whole blood samples on the GEM Premier 3000 is substantially equivalent in performance, intended use, safety and effectiveness to the predicate device: YSI Model 2300 STAT PLUS Glucose and Lactate Analyzer.

# Section 3 (Cont.)
# GEM Premier 3000: Addition of Glucose / Lactate Parameters - 510(k) Summary
# (Summary of Safety and Effectiveness)

**Summary of performance data:**

## Precision

A precision study for glucose and lactate on the GEM Premier 3000 was performed using IL Test™ contrIL 9. Based on NCCLS guidelines, control levels were run in replicates of 2 once a day for 14 days (twice on Day 1) for a total of 30 replicates on 7 different GEM Premier 3000 instruments (N=210).

| | Level 1 | | | Level 2 | | | Level 3 | | |
|---|---|---|---|---|---|---|---|---|---|
| **Parameter** | **Mean** | **Within Run %CV** | **Total %CV** | **Mean** | **Within Run %CV** | **Total %CV** | **Mean** | **Within Run %CV** | **Total %CV** |
| Glucose (mg/dL) | 274.2 | 2.04 | 2.16 | 91.2 | 2.21 | 2.39 | 63.1 | 1.71 | 2.95 |
| Lactate (mmol/L) | 5.06 | 2.13 | 2.41 | 0.97 | 4.11 | 4.23 | 2.78 | 1.46 | 3.02 |

## Method Comparison

The method comparison data included arterial, venous, heart bypass and liver transplant blood samples from hospital patients using heparinized syringes. All samples were analyzed on the GEM Premier 3000 versus a YSI Model 2300 STAT PLUS Glucose and Lactate Analyzer as the predicate device for glucose and lactate. The GEM Premier 3000 was shown to be statistically similar to the predicate device for glucose and lactate:

| Parameter | N | Slope | Intercept | r | Sample Range |
|---|---|---|---|---|---|
| Glucose (mg/dL) | 174 | 0.9871 | 7.6572 | 0.9887 | 23.599-457.423 |
| Lactate (mmol/L) | 172 | 0.9252 | 0.0400 | 0.9877 | 0.529-7.365 |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 7 2001

Ms. Reba Poirier
Regulatory Affairs Process Manager
Instrumentation Laboratory Company
101 Hartwell Avenue
Lexington, MA 02421-3125

Re: 510(k) NUMBER: K010520
Trade/Device Name: GEM Premier 3000 – Addition of Glucose and Lactate (Lactic Acid) as Measured Parameters
Regulation Number: 862.1345
Regulatory Class: II
Product Code: CGA
Regulation Number: 862.1450
Regulatory Class: Class I, exempt
Product Code: KHP
Dated: February 21, 2001
Received: February 22, 2001

Dear Ms. Poirier:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use Statement

**510(k) Number (if known):** K010520

**Device Name:** GEM Premier 3000 – Addition of Glucose and Lactate (Lactic Acid) as Measured Parameters

**Indications for Use:**

The GEM Premier 3000 is a portable system for use by health care professionals to rapidly analyze whole blood samples that was cleared for market by K992834. Two new parameters are being added on the GEM Premier 3000 for the quantitative measurements of glucose and lactate (lactic acid) on whole blood and to its associated quality control materials. These new parameters aid in the diagnosis of the patient's acid/base and glucose status.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010520

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.019)